

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.: 10/804,576
Confirmation No.: 7069
Applicants: Frederick H. Miller
Filed: March 19, 2004
Art unit: 1615
Examiner: Aradhana Sasan
For: **MULTI-PHASE, MULTI-COMPARTMENT
CAPSULAR DELIVERY APPARATUS AND
METHODS FOR USING SAME**

October 9, 2009

Commissioner for Patents
Alexandria, VA 22313-1450

Declaration of Inventor Frederick H. Miller

I, Fred H. Miller, a citizen of the United States and resident of the state of Florida, U.S.A., declare and state as follows:

1. I am the named inventor of the above-referenced patent application. I am also CEO of INNERCAP Technologies, Inc., the assignee of the above-referenced patent application.
2. I am aware that the Examiner has rejected the claims of the above-referenced patent application based on a number of prior art references, namely Bakhshae et al. (WO 02/07710), and the combination of Bakhshae et al. and Rashid et al. (U.S. 5,750,143).

3. I believe that the claims as currently amended in the concurrently filed Amendment place the claims in condition for allowance. However, in the event that the Examiner requires further persuasion, I make this declaration in support of patentability on the basis of the commercial success of products that utilize the claimed technology (hereinafter referred to as the "INNERCAP Technologies' delivery system").
4. The following paragraphs explain the commercial success of INNERCAP Technologies' delivery system in the marketplace.
5. The consumer products industry is highly competitive industry where product differentiation is a key to commercial success. With respect to OTC drug and nutraceutical products, product differentiation can be accomplished through attractive packaging, ingredient list, amounts of key ingredients, quality, dosage form, dosage form visual appeal, price point, use of trademarks, patents and marketing factors.
6. The Sports Nutrition segment is one of the most competitive sectors of the consumer products (nutritional supplements) industry.
7. Consumers are always looking for the newest and most innovative products in the consumer products industry that offer them some benefit over other products. If a product is comparable to or exceeds consumer demand for leading products then it can enjoy commercial success.
8. Therefore, sports nutrition companies that sell products to consumers in the consumer products industry are always looking for the newest ingredients, branded ingredients, trademarks, new dosage forms, delivery systems and marketing concepts to attract consumers to their products.

9. Prior to 2003 most sports nutrition supplements were formulated as liquid drinks, powders, tablets, softgel gelatin capsules and capsules. Encapsulated powder products were considered the premium oral dosage form by companies and consumers due to the ease of swallowing, as well as their price point. The segment was very competitive and the primary product differentiation was created through ingredient lists, packaging, servings per container and marketing.
10. In 2003, a small innovative company named NUTREX Research, Inc. (Oviedo, FL 32765) contemplated using a new dosage form to differentiate their products from competing products. I understand that the two owners of NUTREX Research had a lot of experience developing, marketing and selling consumer products in the U.S. and abroad. They had been selling their sports nutrition supplement products in a powder filled two-piece hard shell capsule dosage form. NUTREX had many competitors selling competing products using the same dosage form, and so they were looking for a way to differentiate their product.
11. I am informed that at that time, NUTREX came across a new capsule dosage form that they believed would have many advantages over the competing products. This new capsule dosage form was a liquid filled two piece hard shell sealed capsule. The new liquid filled capsule was visually appealing because consumers could see that there was a liquid or semi-solid formulation filled into the two-piece hard shell capsule. The new NUTREX dosage form was commercialized under the tradename NUTREX LIPO® 6. It delivered a liquid rather than a powder. I am informed that NUTREX believed that this NUTREX LIPO® 6 product could have a marketing advantage - the product could be positioned and marketed as a faster acting product than other competing products.
12. To my knowledge, NUTREX was the first company to ever introduce a liquid filled two piece hard shell capsule to the sports nutrition consumer products industry.

13. The new NUTREX LIPO 6 product that used the liquid filled two piece hard shell capsule became a huge success, selling millions of dollars per year in leading chain retail stores throughout the USA.
14. Once NUTREX's competitors realized NUTREX's success and the consumer preference for a liquid filled capsule, NUTREX's competitors quickly began to change over their products to the liquid filled dosage form since it was not a patented technology.
15. Over a two year time period, NUTREX ended up having the same issue again where the products of its competitors were similar to NUTREX's products, since they also used a liquid filled capsule delivery system.
16. In 2005 NUTREX began looking for a new delivery system to provide their product with a distinct difference from their competitors' products. At that time, I am informed that NUTREX became aware of the availability of my technology (the INNERCAP Technologies delivery system) through a third party. NUTREX became interested in the INNERCAP Technologies delivery system as a way to reposition their products in the sports nutrition consumer products industry.
17. INNERCAP and NUTREX entered into a license agreement for the INNERCAP Technologies delivery system and shortly thereafter NUTREX started selling a new version of their liquid filled capsule product named LIPO® 6X.
18. The new LIPO 6X product used the INNERCAP Technologies delivery system. The LIPO 6X product is a multi-phase capsule in which an inner capsule contains some of the active ingredients in the form of beadlets and sits inside a liquid (oil) filled capsule. The inner capsule of the LIPO 6X product contains caffeine (anhydrous) among other active ingredients, and the outer capsule contains conjugated linoic acid CLA, linoleic acid and oleic acid.

19. More particularly, the new improved LIPO 6X product using the INNERCAP Technologies delivery system makes it possible to eliminate an undesired effect of the LIPO 6 Product. The licensed technology makes it possible to control the release of the caffeine so that consumers do not feel the undesired effects of a large dose of caffeine all at once on their system (sometimes referred to as a caffeine rush by consumers) and then the undesired effect of the majority of the caffeine wearing off at one time that is commonly referred to as a caffeine crash. The multi-phase multi-compartment capsule allows NUTREX to separate the caffeine from the immediate release liquid phase ingredients in an interior compartment consisting of time release caffeine that controls the release of the caffeine into the consumers system therefore eliminating the full dose onset of the caffeine and undesired negative side effects.
20. NUTREX also sells other products which utilize the INNERCAP Technologies delivery system, such as ANABOL™ 5, which is a multi-phase capsule in which an inner capsule containing an extended release “anabolic amplifier” sits inside a capsule containing a fast-acting liquid (oil). NUTREX currently has five products using INNERCAP Technologies delivery system that NUTREX is currently selling. The primary products with the most sales are the LIPO 6X and Womens LIPO 6X. The Nutrex Research web site is www.nutrex.com.
21. The LIPO 6X product as well as other new NUTREX products developed by and marketed by NUTREX using the licensed INNERCAP Technologies delivery system (such as LIPO 6 HERS, ANABOL™ and IGNITETM™) have been an enormous and immediate commercial success, due to the consumer and retailer demand. In my opinion, this is due in large part to the unique INNERCAP Technologies delivery system.
22. Although INNERCAP is bound by confidentiality constraints, I can state that NUTREX’s products using the INNERCAP Technologies delivery system have

recouped lost sales (of NUTREX earlier liquid filled products due to third party competition) and monthly comparable sales trends have continued to increase.

23. Sports nutrition companies that sell premium priced products in the U.S. achieve the greatest sales success in selling these premium products through nutritional supplement stores such as General Nutrition Centers (GNC) and the Vitamin Shoppe, as well as gyms and other specialty nutritional products stores. NUTREX has achieved commercial success selling the new LIPO 6X through retailers such as GNC stores. The new LIPO 6X product as well as the LIPO 6X Hers have been placed on the shelf alongside the original immediate release LIPO 6 product and the sales of the new products using the patent pending technology licensed from INNERCAP Technologies has exceeded the sales of the LIPO 6X in the GNC Stores. This is despite the current recession in which many consumers have not had the disposable income to purchase the new LIPO 6X product that is sold at a premium price (as compared to the LIPO 6 product).
24. The LIPO 6X product has not only been sold at GNC stores, but it has been a featured product in GNC advertisements and is arranged at featured locations in the stores, such as the cash register counter space which is premium space only offered to the products with the greatest sales potential, as well endcaps. An exemplary GNC advertisements are attached as Exhibit A to my Declaration. It is apparent that these advertisements focus on the benefits of the INNERCAP Technologies delivery system.
25. I understand that currently pending claims of my above-referenced patent application are directed to, *inter alia*, a multi-compartment capsule comprising: a first receiving chamber comprising at least one oil ingredient in immediate release form, wherein said oil ingredient is selected from the group consisting of a nutraceutical, a vitamin, a dietary supplement; and a second receiving chamber containing only solid ingredients and comprising at least one active ingredient in a solid state, formulated in a manner allowing for a time-delayed dissolution and release of said solid active ingredient, wherein said ingredient is selected from

the group consisting of a nutraceutical, a vitamin, a dietary supplement and a mineral, wherein the ingredients of said first receiving chamber is different from the ingredients of said second receiving chamber, and wherein the multi-compartment capsule is a hard shell capsule (claim 141).

26. It is my opinion and belief that at least the pending independent claims of my above-referenced patent application encompass the commercialized products (e.g., LIPO 6X, LIPO 6 HERS, and ANABOL™) that I have discussed herein.
27. I have previously made of record via an Information Disclosure Statement filed on February 12, 2009 the fact that litigation existed between NUTREX and INNERCAP. A copy of NUTREX's Action for Declaratory Judgment and Breach of Contract, as well as INNERCAP's Answer, Affirmative Defenses, and Counterclaims were attached to that Information Disclosure Statement. These documents evidence the existence of a license agreement between the parties, and allegations made by NUTREX concerning patentability, as well as INNERCAP's responses to the same.
28. The litigation between NUTREX and INNERCAP has been settled. A new license agreement is in place, and NUTREX continues to pay royalties to INNERCAP based on the sales of NUTREX products that utilize the INNERCAP Technologies Delivery System.

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29. I declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated:

10/13/2009

Name:

Fred H. Miller

Fred H. Miller

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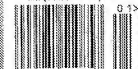
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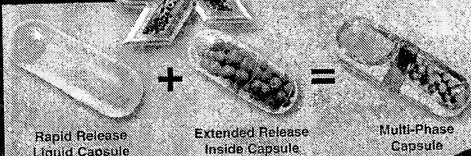


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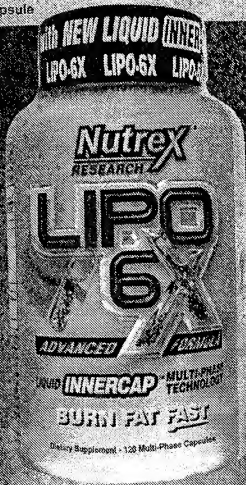
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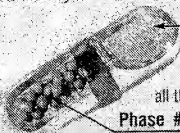
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Phase #1 Rapid Release Liquid Capsule: The outer liquid capsule of Lipo-6X ensures a rapid and almost instant uptake of its appetite-suppressing, fat-burning, thyroid-boosting and energy-promoting ingredients. Within minutes of taking Lipo-6X you will feel all the liquid pharmaceutical-grade compounds working for you.

Phase #2 Controlled and Extended Release Inside Capsule: Unlike standard fat-burning formulas, whose effects come and go quickly, Lipo-6X continues to work for you over an extended period of time. By selectively putting some of the ingredients in the form of pellets into a separate capsule, that sits inside the liquid capsule, the absorption rate can now be controlled. This greatly extends the amount of time these ingredients are active, which means that the appetite-suppressing, thyroid-boosting and fat-burning effects of Lipo-6X continue to work for many hours allowing you to consistently lose weight around the clock.

Lipo-6X is the first and only fat burner that offers speed and duration. A quick and rapid onset of its powerful fat-burning and energy-promoting effects, combined with a controlled and extended release, will ensure maximum results day and night. This newly developed liquid **INNERCAP™** multi-phase technology is so superior that several US Patents are pending and it can only be found in Lipo-6X.

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